

Dalhousie Law Journal

Volume 41 | Issue 1

Article 4

4-1-2018

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Recommended Citation

Oliver J. Kim, "Trying and Dying: Are Some Wishes at the End of Life Better Than Others?" (2018) 41:1 Dal LJ 93.

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Oliver J. Kim*

Trying and Dying: Are Some Wishes at the End of Life Better Than Others?

In the United States, efforts to create a "right to try," or to provide access for the terminally ill to try experimental drugs, have seen overwhelming success in passing state legislatures. This success provided the foundation for advocates' long-term goal of a federal right to try. Yet proposals ranging from very modest advance-care-planning consultations to the "right to die," or medical aid in dying, face steep political challenges despite seeming public support.

This paper discusses the legal underpinnings of both "rights" and the current political and policy debate over each. More often than not, these "rights" are granted through legislation rather than judicial decisions, and the US Supreme Court has held that neither "right" can be found in the Constitution. This debate says a lot not only about politics in the United States but also our policies around autonomy at the end of life.

Aux États-Unis, les efforts visant à créer un « droit à l'essai » ou à permettre aux malades en phase terminale d'avoir accès à des médicaments expérimentaux ont connu un succès retentissant dans l'adoption des lois par les États. Ce succès a jeté les bases de l'objectif à long terme des défenseurs du droit fédéral à l'essai. Pourtant, des propositions allant de très modestes consultations de planification préalable des soins au « droit de mourir », ou à l'aide médicale à la mort, se heurtent à des défis politiques de taille malgré un soutien public apparent.

Le présent document examine les fondements juridiques des deux « droits » et le débat politique et politique qui a cours actuellement sur chacun d'eux. Le plus souvent, ces « droits » sont accordés par voie législative plutôt que par des décisions judiciaires, et la Cour suprême des États-Unis a statué que ni l'un ni l'autre « droit » ne se trouve dans la Constitution. Ce débat en dit long non seulement sur la politique aux États-Unis, mais aussi sur nos politiques en matière d'autonomie en fin de vie.

* JD, University of Minnesota; LLM, Georgetown University Law Center. This article is based on my presentation at the Second International Conference on the End of Life, and I would like to thank Kathryn Kietzman, Lois Magner, Cara Tenenbaum, Ken Brummel-Smith, and Tanya Harris for advice and suggestions.

Introduction

- I. *The right to try and its impact on the drug approval process in the United States*
 1. *The history and basic structure of the drug approval process in the United States*
 2. *Efforts to allow patients to take drugs not yet approved*
 - a. *Administrative remedies: FDA allowance for expanded use/compassionate use for people not in clinical trials*
 - b. *Failed attempts at judicial remedies*
 - c. *Statutory remedies*
- II. *The right to die and related issues*
 1. *Federal law and policy*
 - a. *Federal jurisprudence: no recognition of a constitutional right*
 - b. *Federal policies around end-of-life options*
 2. *State law and policy*
- III. *Comparing and contrasting the right to try with the right to die and related policies*
 1. *Policy and ethical considerations*
 2. *Legal questions arising from the political and ethical similarities*

Conclusion

Introduction

One of the most difficult and controversial issues for policymakers is how to ensure the law respects a patient's wishes at the end of life. Some policymakers have proposed granting individuals suffering from terminal illness a "right to die," or to seek medical assistance to end their life. Another policy proposal is the so-called "right to try," or providing a means for terminally ill patients to request experimental drugs that have not completed clinical trials to demonstrate they are safe and effective. Essentially, both policies purport to give individuals more autonomy at the end of life, but Congress and the majority of states have passed right-to-try bills while proposals ranging from very modest advance-care-planning

consultations to the right to die, or medical aid in dying, often face steep political challenges despite strong public support.¹

Notably when either “right” has been granted, it generally has been by the legislature, not the judiciary. For better or for worse, such grants inject a political element into the creation of that right. Here, the debate says a lot, not only about politics in the United States, but also about our policies around end-of-life decision-making. While we want a society that values life, we also want a society that empowers individuals to make their own decisions, particularly about their health and well-being.

The division between the two issues can be illustrated by two unrelated legislative initiatives that were being debated in Congress almost simultaneously in 2015. In one chamber, the House of Representatives overwhelmingly passed the *21st Century Cures Act*,² legislation mainly aimed at increasing research funding and streamlining the drug and device approval process. Tucked within this massive bill was an attempted compromise around a right to try.³ In the other chamber, the Senate unanimously passed a reauthorization of the *Older Americans Act*,⁴ a fifty-year-old package of authorizations for aging programs ranging from nutrition to legal services to caregiver supports. But an amendment to authorize resources to service organizations to provide end-of-life counseling, or advance care planning, failed to be included.⁵ While it is unclear from the statement from the amendment’s sponsor why the amendment failed to be included,⁶ an observer of American politics may wonder if the amendment failed due to lingering concerns over claims of

1. Paige Winfield Cunningham, “Legalizing assisted suicide has stalled at every level,” *Washington Post* (24 October 2017), online: <<https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2017/10/24/the-health-202-legalizing-assisted-suicide-has-stalled-at-every-level/59ee109330fb045cba000973/>>.

2. H.R. 6, 114th Cong. (2015). US Bill HR 6, *21st Century Cures Act*, 114 Cong. 2015.

3. Andy Taylor & Alison Bateman-House, “Right to try misses the real issue. There is another solution,” (20 December 2016), *The Hill* (blog), online: <thehill.com/blogs/congress-blog/healthcare/311259-right-to-try-misses-the-real-issue-there-is-another-solution> (discussing an attempt by the provision’s authors to create “unglamorous but effective bipartisan solutions that will help patients now and in the future by giving them better information and providing transparency into the expanded access process”).

4. US, Bill S 192, *Older Americans Act Reauthorization Act of 2016*, 114th Cong. 2016.

5. US, Cong Rec, daily ed, vol 161, 111 at S 5154 (16 July 2015) (statement of Sen. Sheldon Whitehouse on the Older Americans Act).

6. *Ibid* (referencing “difficulties” with including the amendment).

“death panels”⁷ hurting the chances of passing an otherwise uncontroversial bill.

This article discusses the legal underpinnings of both rights and the current political and policy debate over each. First, Part I will discuss the development of the right to try; this discussion necessitates a brief review of the drug development and approval process in the United States. Second, Part II will review efforts to pass end-of-life policies from educating individuals about end-of-life choices to state laws to provide medical aid in dying. Part III will then compare and contrast the competing rights and discuss where advocates for greater end-of-life policies could learn from the right-to-try movement. My hope is that this analysis is not only instructive in the American legal and political debate but also informs other countries’ discussions over end-of-life policy-making.⁸

I. *The right to try and its impact on the drug approval process in the United States*

Prescription drugs are a critical part of many healthcare systems, including the United States where drugs consume ten percent of the country’s total healthcare spending.⁹ Drugs have increased longevity, and given their importance in the lives of many Americans, our federal government has attempted to balance the availability of new drugs with an approval process that protects the public’s health from unsafe and dangerous products. At

7. The term “death panels” refers to a claim made in opposition to the Affordable Care Act that passing a national health reform bill would lead to rationing of care and that an early version’s proposal to include reimbursement for end-of-life consultations would lead to such panels. Don Gonyea, “From the Start, Obama Struggled With Fallout From A Kind of Fake News,” *NPR Politics* (10 January 2017), online: <www.npr.org/2017/01/10/509164679/> (providing an overview of the term and its effect). As discussed below, such consultations were eventually allowed years later. Compare Robert Pear, “New Medicare Rule Authorizes ‘End-of-Life’ Consultations,” *New York Times* (30 October 2015), online: <www.nytimes.com/2015/10/31/us/new-medicare-rule-authorizes-end-of-life-consultations.html> (discussing how Medicare would pay for “consultations with patients on how they would like to be cared for as they are dying” six years following the “death panels” debate) with Avik Roy, “Death Panels Through the Back Door,” *National Review* (29 December 2010), online: <www.nationalreview.com/critical-condition/death-panels-through-back-door-avik-roy/> (criticizing a prior proposal to have Medicare pay for such consultations “because it has every incentive to encourage the elderly to ‘pull the plug’ instead of encouraging them to fight to stay alive”).

8. For scholarship on these debates outside the United States, see as examples Denise Meyerson, “Medical Negligence Determinations, the ‘Right to Try,’ and Expanded Access to Innovative Treatments” (2017) 14:3 *J Bioethical Inquiry* 385; Barbara von Tigerstrom & Emily Harris, “Access to Experimental Treatments: Comparative Analysis of Three Special Access Regimes” 24 *JL & Medicine* 119 (2016); Elizabeth Woods, “The Right to Die With Dignity With the Assistance of a Physician: An Anglo, American and Australian International Perspective” (1998) 4:2 *ILSA J Int’l & Comp L* 817.

9. National Center for Health Statistics, Centers for Disease Control & Prevention, “Health Expenditures” (3 May 2017), online: <www.cdc.gov/nchs/fastats/health-expenditures.htm> (finding that 10.1% of the national health expenditures goes toward prescription drugs).

issue are the political, policy, and ethical issues that determine where the law should strike this balance.

1. *The history and basic structure of the drug approval process in the United States*

Beginning with the 1906 *Pure Food and Drugs Act*,¹⁰ the American federal government has exercised increasing control over the sale, marketing, and production of pharmaceutical products, often in response to public outcry. For instance, Congress passed the *Food, Drug, and Cosmetic Act*¹¹ in response to over a hundred people dying from an elixir that contained antifreeze, and this Act ushered in the modern American drug regulatory process.¹² The new law provided the Food and Drug Administration (FDA) with regulatory authority to require pre-market approval for new drugs with the burden on the drug maker to prove to the FDA that its drug was safe before it could be sold.¹³ Congress increased the FDA's scrutiny by adding proof of efficacy with the 1962 Kefauver-Harris Amendment, which was passed in response to public outrage over the sedative thalidomide.¹⁴

Today, the FDA serves as a "gatekeeper"¹⁵ to protect public health by using its regulatory authority over the drug approval process.¹⁶ To obtain such approval, a drugmaker must go through several stages of clinical trials—often time-consuming and expensive—before a product can receive approval for sale.¹⁷ First, after testing a potential product on animals and other methods, a company can file for an investigational new drug (IND) application to begin to clinical trials on human subjects. In essence, the FDA is issuing a narrow approval of this experimental

10. *Pure Food and Drug Act*, Pub L No 59-384, 34 Stat 768 (1906).

11. *Food, Drug, and Cosmetic Act*, Pub L No 75-717, 52 Stat 1040 (1938).

12. Michelle Meadows, "Promoting Safe and Effective Drugs for 100 Years," *FDA Consumer* (January 2006), online: <www.fda.gov/downloads/AboutFDA/WhatWeDo/History/FOrgsHistory/CDER/UCM586463.pdf>.

13. *Ibid.* However, as a compromise with the drug industry at the time, the FDA had six months to respond to an application; if the FDA failed to object to the application within the statutory timeframe, it would be considered approved.

14. *Ibid.*

15. Patricia Zettler, "Pharmaceutical Federalism" (2017) 92:3 Ind LJ 845 at 857-858.

16. 21 USC § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application...is effective with respect to such drug.") The FDA has expedited processes to allow for the approval of generic drugs, 21 USC § 355(j), and the sale of over-the-counter medicines, Consumer Healthcare Products Association, "FAQs About the Regulation of OTC Medicines," online: <www.chpa.org/FAQsRegOTCs.aspx> (discussing the use of drug monographs in lieu of FDA pre-approval for the sale of over-the-counter drugs, or drugs available without a prescription).

17. US, Office of the Assistant Secretary for Planning and Evaluation, US Department of Health and Human Services, *Examination of Clinical Trial Costs and Barriers for Drug Development* (25 July 2014), online: <aspe.hhs.gov>.

drug solely for the participants in the clinical trial.¹⁸ After three phases of clinical trials involving increasing numbers of subjects, the company can submit its results for a new drug application (NDA). The FDA reviews the NDA to determine the safety and effectiveness in the drug's proposed use, the appropriateness of the drug's proposed labeling, and the adequacy of manufacturing methods to assure the drug's identity, strength, quality, and purity. Even if the FDA approves a NDA, that may not be the final step: while all drugmakers are supposed to report post-market adverse events to the FDA, the FDA can require a drugmaker to conduct post-approval, post-market studies of drugs.

2. *Efforts to allow patients to take drugs not yet approved*

The FDA's extensive authority over drug approval and marketing has not gone unchallenged.¹⁹ While Congress and the public have demanded greater regulatory authority during times of crises, the pendulum has swung toward deregulation when the public feels that the FDA's process has slowed or even blocked access to life-saving medicine. Right-to-try advocates have tried administrative, legislative, and judicial remedies in their efforts to expand access to experimental drugs.

a. *Administrative remedies: FDA allowance for expanded use/compassionate use for people not in clinical trials*

Given its role in the drug approval process, the FDA must balance its role in protecting public health and safety with expediting approval of new drugs and devices for patients in need.²⁰ Some patient advocates have expressed frustration with what they see as government bureaucracy holding back scientific breakthroughs. Within the constraints of its authorizing legislation, the FDA has attempted to address these frustrations by allowing for the "compassionate use" of experimental drugs still in the clinical-trial phase.²¹

18. Susan Thaul, "Access to Unapproved Drugs: FDA Policies on Compassionate Use and Emergency Use Authorization," *Congressional Research Service Report* (4 August 2015).

19. Zettler, *supra* note 15 at 849-850; Lars Noah, "State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products" (2016) *Mich State L Rev* 1 at 2-27.

20. US, Food & Drug Administration, "Expanded Access (Compassionate Use)" (3 October 2017), online: <www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm> ("Ensuring patient safety is a priority—FDA must determine that the potential patient benefit justifies the potential risk of the expanded access use of the investigational drug, and that the potential risk is not unreasonable in the context of the disease or condition to be treated. Even with safeguards, there may be significant unknowns about safety and effectiveness.")

21. *Ibid.*

Becoming more formalized in the 1980s in response to the AIDS crisis,²² the FDA began allowing for IND exemptions to allow drugmakers to give experimental drugs to seriously ill patients. However, the FDA cannot compel a drugmaker to provide the experimental drug to the patient; essentially, the drugmaker basically is agreeing to provide the experimental drug under a new IND for “expanded access”²³ or a “protocol amendment”²⁴ to the clinical trial.²⁵ Spurred by increasing congressional scrutiny²⁶ and criticism that compassionate-use applications were too complicated for many patients and their physicians,²⁷ the FDA has tried to make the process simpler for patients to use.²⁸ The new form is a single page to be filled out and submitted by the patient’s physician to the FDA for a 30-day review;²⁹ however, the physician can expedite the process if the patient’s situation is so dire that 30 days is too long.³⁰ According to its online reports on compassionate-use requests, the FDA approves nearly all the requests it receives.³¹

Despite the revisions and the FDA’s approval of nearly all compassionate-use requests, right-to-try proponents argue that the

22. Laura Kimberly et al, “Pre-approval Access Terminology: A Cause for Confusion and a Danger to Patients” (2017) 51:4 *Therapeutic Innovation & Regulatory Science* 494 at 495.

23. “Expanded Access,” *supra* note 20.

24. US Food & Drug Administration, “Investigational New Drug (IND) Application” (5 October 2017), online: <www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm>.

25. Alexander Gaffney, “From 100 Hours to 1: FDA Dramatically Simplifies its Compassionate Use Process,” *Regulatory Affairs Professional Society, Regulatory Focus* (4 February 2015), online: <www.raps.org/Regulatory-Focus/News/2015/02/04/21243/From-100-Hours-to-1-FDA-Dramatically-Simplifies-its-Compassionate-Use-Process/>.

26. Christina Sandefur, “Safeguarding the Right to Try” (2017) 49:2 *Ariz St LJ* 513 at 552 (“In June 2014, it inspired an investigation of the FDA’s compassionate use process by Senators Tom Coburn, Richard Burr, and Lamar Alexander, and the introduction of a bill in the House of Representatives to prevent the FDA from blocking implementation of any state right-to-try law. In May 2016, the U.S. Senate held hearings on the issue of access to investigational drugs, and a Senate bill complementing the House proposal was introduced that same month.”)

27. Richard A Moscicki, “Important steps toward streamlining access to investigational drugs for patients in need” (21 June 2016) *FDA Voice* (blog), online: <blogs.fda.gov/fdavoic/index.php/2016/06/important-steps-toward-streamlining-access-to-investigational-drugs-for-patients-in-need/>.

28. Gaffney, *supra* note 25.

29. *Individual Patient Expanded Access Applications: Form FDA 3926; Draft Guidance for Industry; Availability*, 80:27 *Fed Reg* 7318 (2015).

30. Gaffney, *supra* note 25.

31. The FDA has made publically available the number of requests and approvals since 2010 at “Expanded Access INDs and Protocols,” online: <<http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/drugandbiologicapprovalreports/inactivityreports/ucm373560.htm>>. In 2015, for example, the FDA approved the vast majority of these requests: over 99 percent of nearly 1,900 applications in 2015. Ed Silverman, “21st Century Cures would require pharma to post policies on experimental drugs,” *STAT Pharmalot* (28 November 2016), online: <<https://www.statnews.com/pharmalot/2016/11/28/21st-century-experimental-drugs/>>.

compassionate-use process still too burdensome for terminally ill patients.³² Even if nearly all the requests are approved, proponents argue that it is impossible to know how many patients and physicians did not apply for a compassionate-use exemption because of concerns about time or the complexity of the process.³³ Congress, too, has criticized the FDA because there is insufficient evidence to determine whether its compassionate-use policy is effective.³⁴ However, the FDA itself can only do so much because it not only needs to protect the integrity of the clinical-trial process but also must follow its authorizing statute regarding who can and cannot take a drug that has not yet been approved.³⁵

b. *Failed attempts at judicial remedies*

In addition to pressuring the FDA directly, right-to-try proponents have challenged the agency's decisions through the courts. In *United States v Rutherford*,³⁶ a group of cancer patients sued the FDA to allow them access to Laetrile, a controversial substance that had not been approved by the FDA but was being used by these patients to aid their treatment.³⁷ The Supreme Court sided with the FDA, deferring to the agency's interpretation of the authorizing statute as reasonable and noting the legislative history strongly supported the FDA's mission to ensure the safety of drugs for all patients, including those with a terminal illness.³⁸

Years later, the Abigail Alliance, a patient advocacy organization, brought a different claim against the FDA by arguing the agency was

32. Christina Corieri, "Everyone Deserves the Right to Try: Empowering the Terminally Ill to Take Control of their Treatment" *Goldwater Institute Policy Report* 266 (11 February 2014) (proposing legislative findings for a bill).

33. Silverman, *supra* note 31.

34. Letter from US Senators Lamar Alexander, Tom Coburn, & Richard Burr to Margaret Hamburg, Commissioner of the FDA (16 June 2014), published in US Senate Committee on Health, Education, Labor, and Pensions, "Senators Ask FDA about Expanded Access Program in Response to Patient Concerns" (18 June 2014), online: <<https://www.help.senate.gov/chair/newsroom/press/senators-ask-fda-about-expanded-access-program-in-response-to-patient-concerns>>; US Congressman Michael McCaul, Press Release "McCaul Language to Explore 'Compassionate Use' Passes Appropriations Committee" (30 May 2014), online: <<http://mccaul.house.gov/media-center/press-releases/mccaul-language-to-explore-compassionate-use-passes-appropriations>>.

35. *Supra* note 20. Even if the FDA does grant a compassionate use exemption, it cannot compel the drug maker to make the experimental drug available. US, Food and Drug Administration, *Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers* (October 2017) at 17; Silverman, *supra* note 31.

36. 442 US 544 (1979).

37. Morton Mintz, "Supreme Court enters quarrel over Laetrile," *Washington Post* (23 January 1979), online: <https://www.washingtonpost.com/archive/politics/1979/01/23/supreme-court-enters-quarrel-over-laetrile/871f8e04-8380-4c89-b6be-5d2ed752d55c/?utm_term=.2e323b24e1e3>.

38. *Rutherford*, 442 US, *supra* note 36 at 553. ("In implementing the statutory scheme, the FDA has never made exception for drugs used by the terminally ill. As this Court has often recognized, the construction of a statute by those charged with its administration is entitled to substantial deference.")

violating terminally-ill patients' fundamental rights under the Fourteenth Amendment by denying them access to experimental drugs.³⁹ In particular, the Abigail Alliance noted that the FDA was conceding that these drugs were "safe and promising enough" to be available for some patients—the ones participating in the clinical trials.⁴⁰

Although the plaintiffs won their initial appeal, the DC Circuit ultimately ruled *en banc* that there was no constitutional right at risk and thus the plaintiffs did not have a claim that relief could be granted. The DC Circuit began by tracing the evolution of the drug approval process as part of "our Nation's history, legal traditions, and practice."⁴¹ The court noted that Congress rejected the drug industry's claim that Americans would lose "the right to self-medication" when it passed the *Food, Drug, and Cosmetic Act*—a claim that paralleled the Abigail Alliance's central argument.⁴² And even if Congress did not include efficacy as part of the FDA's review until the 1962 amendments, the court reasoned that the arc of history moved towards protecting the public by adopting policy changes to keep up with scientific developments.⁴³

Further, the court noted that terminally-ill patients do not need to wait until a clinical trial is over because the "FDA and Congress have created several programs designed to provide early access to promising experimental drugs when warranted."⁴⁴ Thus, there was a remedy that had been created within the appropriate "arena of public debate and legislative action," not by the "policy preferences" of the judiciary.⁴⁵ The court concluded that the Abigail Alliance's "arguments about morality, quality of life, and acceptable levels of medical risk are certainly ones that can be aired in the democratic branches, without injecting the courts into unknown questions of science and medicine."⁴⁶ Subsequently, the Supreme Court denied cert, essentially leaving *Abigail Alliance* as the final decision on whether terminally ill patients have a substantive due process right to access experimental drugs.

39. *Abigail Alliance, Better Access v von Eschenbach*, 495 F (3d) 695 (DC Cir 2007) (en banc).

40. *Ibid* at 701-703. The plaintiffs' argument seemingly suggests that but for the FDA's regulatory restrictions, the drug maker would provide the experimental drugs to terminally ill patients.

41. *Ibid* at 703.

42. *Ibid* at 705.

43. *Ibid* at 706-707.

44. *Ibid* at 698-699; also Section I(B)(1) above.

45. *Abigail Alliance, ibid* at 702.

46. *Ibid* at 713.

c. *Statutory remedies*

With no judicial recognition of a right to try experimental drugs and frustration with the FDA's administrative process for compassionate use, patient advocates turned to the legislative process for relief. This advocacy led to the right-to-try movement, which has seen remarkable success at the state and federal level. While the initial state laws could not change the federal drug approval process and may have been on questionable legal and policy grounds, they provided a successful foundation for political pressure on Congress to enact a statutory change.

State legislation

Beginning with Colorado in 2014, a majority of states have enacted "right-to-try" laws, which follow model legislation drafted by the libertarian Goldwater Institute.⁴⁷ One draft of the Goldwater model legislation is explicitly critical of the FDA drug approval process: "The use of available investigational drugs, biological products, and devices is a decision that should be made by the patient with a terminal disease in consultation with his or her physician *not a decision to be made by the government.*"⁴⁸

Under the model legislation, patients are only eligible for this statutory-created "right" if they meet certain criteria: the patient must be suffering from an "[a]dvanced illness...that, without life-sustaining procedures, will soon result in death;" have consulted with a physician and considered all other options currently approved by the FDA; have been given a prescription or a recommendation from a physician for an experimental drug; and have given written informed consent to take the experimental drug.⁴⁹ The model does allow the drugmaker to charge for any costs associated with the production of the experimental drug.⁵⁰ Lastly, the model provides immunity for health professionals from the relevant licensing boards for recommending, prescribing, or administering the experimental drug.⁵¹

47. Goldwater Institute, "Right to Try Model Legislation," online: <[https://goldwaterinstitute.org/wp-content/uploads/cms_page_media/2015/1/28/RIGHT%20TO%20TRY%20MODEL%20LEGISLATION%20\(2\)_1.pdf](https://goldwaterinstitute.org/wp-content/uploads/cms_page_media/2015/1/28/RIGHT%20TO%20TRY%20MODEL%20LEGISLATION%20(2)_1.pdf)> (hereinafter "Model Legislation"). Note that there have been prior attempts to legislate greater access to experimental drugs. Susan Okie, "Access before Approval—A Right to Take Experimental Drugs?" (2006) 355:5 New Eng J Med 437 at 439 (discussing a 2005 U.S. Senate bill that would allow terminally ill to obtain any drug that had gone through the first phase of clinical trials).

48. Corieri, *supra* note 32 at 2 (proposing legislative findings for a bill) (emphasis added).

49. Model Legislation, *supra* note 47 at section 1.

50. *Ibid* at Section 2. The FDA also limits what a drug maker can charge for experimental drugs in a clinical trial. 21 CFR § 312.8 (2009).

51. Model Legislation, *supra* note 47 at section 5.

However, the legislation contains a number of legal and structural flaws that make effectuating the right to try difficult. The model right-to-try legislation explicitly does not mandate drugmakers to actually provide the experimental drug.⁵² Drugmakers may have many reasons for not supplying an experimental drug to individuals outside the clinical trials.⁵³ Even if the company does agree to supply the patient with the drug, the company can charge the patient for all costs associated with the experimental drug, and the legislation explicitly states the patient's insurer is not required to cover any costs associated with the experimental drug.⁵⁴ This financial situation is very different from patients who are actually in a clinical trial.⁵⁵ Given these high hurdles, it is not clear if any patient actually has been aided by a state right-to-try law.⁵⁶

Second, there is only so much that a state statute can accomplish in an area as heavily regulated by the federal government as the drug approval and marketing process.⁵⁷ In the American federalist system, states can be preempted from regulating in an area when the federal government is lawfully exercising its regulatory authority as either the exclusive regulator or because it is regulating an area so expansively that there is no

52. *Ibid* at Section 2.

53. Silverman, *supra* note 31. ("For instance, an unexpected patient reaction may jeopardize the chance that a clinical trial will succeed or a company may lack sufficient supplies of their drug."); Laurie McGinley, "Are right-to-try laws a last hope for dying patients—or a false hope?," *Washington Post* (26 March 2017), online: <www.washingtonpost.com/national/health-science/are-right-to-try-laws-a-last-hope-for-dying-patients--or-a-cruel-sham/2017/03/26/1aa49c7c-10a2-11e7-ab07-07d9f521f6b5_story.html?utm_term=.fc64c292ae4e> ("Manufacturers, they say, don't like to provide experimental therapies in part because they don't want to be besieged by desperate patients but also because of the potential cost involved."); Okie, *supra* note 47 at 440 (noting that manufacturing capacity is a limitation for drug makers "[e]specially in very early phases, [because] the company may still be working out how to manufacture the product").

54. Model Legislation, *supra* note 47 at sections 3 and 7. There may be other costs, too, such as institutional review board reviews. Meyerson, *supra* note 8 at 395.

55. See *infra* notes 84-87.

56. NYU Langone Health Working Group on Compassionate Use and Pre-Approval Access, "How many patients have been helped by right-to-try laws so far?," online: <med.nyu.edu/pophealth/divisions/medical-ethics/compassionate-use#Q11>. ("To the best of our knowledge, no patients have been spared from death by right to try laws.")

57. Caitlyn Martin, "Questioning the 'Right' in State Right to Try Laws: Assessing the Legality and Effectiveness of These Laws" (2016) 77:1 Ohio St LJ 159 at 178-181 (discussing express and implied preemption of state laws particularly in the context of regulating drugs); see also *PLIVA v. Mensing*, 564 US 604 at 611-624 (2011) (finding that federal regulations on generic drug labelling preempted a state tort claim). There are examples, however, of state regulatory efforts, often in the area of product liability or medical practice, that challenge the conventional wisdom of federal preemption in this area. Zettler, *supra* note 15 at 861-888 (discussing different state regulatory schemes, including the right to try, that were justified under traditional state powers of regulating product liability and the practice of medicine); Noah, *supra* note 19 at 4-26 (discussing state attempts to ban the sale of an FDA-approved drug); Meyerson, *supra* note 8 at 397.

room for state regulation.⁵⁸ Proponents argue that state right-to-try laws complement, rather than try to supplant, the FDA process and thus are not preempted.⁵⁹ Although it is an open question whether state right-to-try laws are preempted by the FDA's authority,⁶⁰ a court potentially could find the FDA compassionate-use process has implicitly preempted state right-to-try laws because it is the exclusive means for obtaining access to these experimental drugs.⁶¹ Regardless, the overwhelming response in the states set the foundation for seeking federal policy,⁶² and a federal law could address any potential legal concerns.⁶³

Federal legislation

The same political forces that influenced efforts at the state level similarly have moved Congress to pressure the FDA to revise its compassionate-use policy and even to introduce legislation to authorize a federal right to try.⁶⁴ At the same time, new conservative leadership in Congress⁶⁵ and the federal government⁶⁶ favoured greater deregulation. Thus, the political

58. Martin, *ibid.*

59. Meyerson, *supra* note 8 at 397. ("It is possible to comply with both the Right to Try laws and the FDA regulations, since the state laws do not oblige anyone to violate federal law by providing access to investigational products outside of FDA processes."); Zettler, *supra* note 15 at 851. ("Today, the federal government rigorously regulates drugs—drugs generally cannot be sold, prescribed, or dispensed to patients until the federal government determines that they are safe and effective.")

60. Ellen Black, "State 'Right to Try' Acts: A Good Start, but a Federal Act is Necessary" (2016) 45:3 Sw L Rev 719 at 743. ("As many legal scholars have argued, it appears likely that the right to try acts are impliedly preempted by the FDA regulations."); Martin, *supra* note 57 at 182-183. ("Right to Try laws, however, remove safeguards governing the accessibility of drugs by circumventing the FDA altogether.")

61. Martin, *supra* note 57 at 178-85; see also Rutherford, 442 US *supra* note 37 at 558 (1979). ("To accept the proposition that the safety and efficacy standards of the Act have no relevance for terminal patients is to deny the Commissioner's authority over all drugs.")

62. Meyerson, *supra* note 8 at 397 (noting that regardless of legality under the US Constitution, state laws' "real objective is to exert pressure on the federal government to revisit the issue of access").

63. Black, *supra* note 60 at 751-752.

64. *Supra* note 34 and *infra* note 67; see also Sam Adriance, "Fighting for the 'Right to Try' Unapproved Drugs: Law as Persuasion" (2014) 124 Yale LJ Forum 148 at 149 (arguing that "even when federal law ensures that states lack legal power to alter substantive law meaningfully, state actors can still use their legislative processes to promote their desired policies and constitutional interpretations at the federal level").

65. Deborah Mazer & Gregory Curfman, "21st Century Cures Act Lowers Confidence in FDA-Approved Drugs and Devices" (14 February 2017) *Health Affairs Blog*, online: <healthaffairs.org/blog/2017/02/14/21st-century-cures-act-lowers-confidence-in-fda-approved-drugs-and-devices/>; Public Citizen, "Stop the 21st Century Cures Bill," online: <www.citizen.org/our-work/health-and-safety/stopping-legislative-attacks-fda-regulation>.

66. Renée Landers, "Scott Gottlieb's fervor for deregulation could harm patients," *STAT* (16 March 2017), online: <www.statnews.com/2017/03/16/scott-gottlieb-fda-deregulation/>; Sheila Kaplan, "Trump order on regulations could create hurdles for FDA, Cures Act," *STAT* (30 January 2017), online: <www.statnews.com/2017/01/30/fda-regulations-executive-order-trump/>.

climate was ripe to successfully push Congress to pass legislation to create a federal right to try in 2018.⁶⁷

Although the federal right-to-try law explicitly retains the compassionate-use process,⁶⁸ it creates a new national process for patients to request access from a drug maker directly without seeking FDA approval. The federal right-to-try law defines an eligible patient as one who has been diagnosed with a life-threatening disease or condition;⁶⁹ has exhausted approved treatment options and cannot participate in the experimental drug's clinical trial, as certified by a physician in good standing and who is not receiving any direct compensation from the drugmaker; and has given written informed consent.⁷⁰ The law also lifts a potential barrier for many drugmakers by prohibiting the FDA from using "a clinical outcome associated with the use of an eligible investigational drug pursuant to" the Johnson bill.⁷¹ It precludes liability for the drugmaker and the health professional who prescribes or dispenses the experimental drug without a showing of misconduct, gross negligence, or similar intentional tort.⁷² Finally, the federal right-to-try law explicitly states the drugmaker is not liable if it decides not to provide access to an experimental drug,⁷³ and this protection is further buttressed by legislative intent explicitly stating that

67. US Bill S 204, *Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act*, 115th Cong, 2017 (enacted). The legislation's sponsor, Senator Ron Johnson of Wisconsin, has had a long-standing interest in the right to try. See US, *Connecting Patients to New and Potential Life Saving Treatments: Hearing Before the Senate Committee on Homeland Security & Government Affairs*, 114th Cong (2016), online: <www.hsgac.senate.gov/hearings/connecting-patients-to-new-and-potential-life-saving-treatments> (hosting a hearing on access to experimental drugs). Johnson used a procedural mechanism to hold up a reauthorization of the FDA's user fee program in order to pass his bill through the Senate. Sarah Karlin-Smith & Seung Min Kim, "Senate approves 'right-to-try' drug bill," *Politico* (3 August 2017), online: <www.politico.com/story/2017/08/03/senate-right-to-try-drug-bill-241293>. Although the House passed an alternate version that was favored by the FDA, the House ultimately passed the Johnson version. Erin Mershon, "Congress passes 'right-to-try' measure, sending hard-fought bill to Trump's desk," *STAT* (22 May 2018), online: <<https://www.statnews.com/2018/05/22/house-vote-right-to-try/>>.

68. *Ibid.*, S 204 § 3(4) (stating that the Johnson bill "is consistent with, and will act as an alternative pathway alongside, existing expanded access policies").

69. *Ibid.*, S 204 § 2(a) refers to 21 CFR § 312.81 to define "life-threatening" as "(1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted; and (2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival." This definition is different than the standard set in the Goldwater model legislation because the disease does not need to be terminal where the threat of death is imminent.

70. *Ibid.*

71. *Ibid.*, § 2(c). However, the Johnson bill does allow the FDA to consider such data if it is found to be "critical to determining the safety of" the experimental drug or if the drug maker requests its inclusion.

72. *Ibid.*, § 2(b).

73. *Ibid.*

Congress does not intend the legislation to establish a new entitlement or a new mandate.⁷⁴

Not everyone supported these developments as many ethicists, scientists, former regulatory officials,⁷⁵ and even patient and consumer groups raised policy and ethical concerns about how a federal right to try would affect the drug approval process.⁷⁶ Patient advocates have noted that because experimental drugs are still in clinical trials, drugmakers may not know the full extent of “worst outcomes.”⁷⁷ By including the FDA through the compassionate-use process, patients may receive critical information and reduce risk of harm because of the FDA’s greater access to data from its work with multiple drugmakers.⁷⁸ Some right-to-try critics also have noted that drugmakers may have their own policies governing when to grant a compassionate use exemption,⁷⁹ and in response to concerns

74. *Ibid.*, § 3.

75. Laurie McGinley, “Former FDA commissioners say right-to-try bills could endanger ‘vulnerable patients,’” *Washington Post* (18 March 2018), online: <www.washingtonpost.com/news/to-your-health/wp/2018/03/18/former-fda-commissioners-say-right-to-try-bills-could-endanger-vulnerable-patients/?utm_term=.1c79b3da02b7> (discussing a letter signed by two FDA commissioners appointed by President Obama and two appointed by President George W. Bush).

76. Rachel Roubein, “Patient groups criticize ‘right to try’ bill on experimental drugs,” *The Hill* (13 March 2018), online: <thehill.com/policy/healthcare/378127-patient-groups-criticize-right-to-try-bill-on-experimental-drugs> (noting that more than 75 patient organizations wrote congressional leadership opposing right-to-try legislation); Andy Taylor & Alison Bateman-House, “Right to try misses the real issue. There is another solution” (12 December 2016) *The Hill* (blog), online: <thehill.com> (discussing opposition in the patient and research community for ethical and scientific reasons).

77. Bob Tedeschi, “With patients demanding experimental drugs, ‘right to try’ is becoming the law of the land,” *STAT* (23 March 2017), online: <www.statnews.com/2017/03/23/right-to-try/>. Despite the President’s support for a right to try, FDA Commissioner Scott Gottlieb voiced concerns about such a policy for many of the reasons cited elsewhere in this paper. Shannon Firth, “FDA Head Expresses Doubt About ‘Right to Try,’” *MedPage Today* (4 October 2017), online: <www.medpagetoday.com/washington-watch/fdageneral/68310>. Since the bill’s passage into law, however, Gottlieb has signalled that the agency would “stand ready to implement this legislation in a way that achieves Congress’ intent to promote access and protect patients.” FDA Press Announcements, “Statement from FDA Commissioner Scott Gottlieb, M.D., on the signing of the Right to Try Act,” (30 May 2018), online: <www.fda.gov/newsevents/newsroom/pressannouncements/ucm609258.htm>.

78. *Ibid.*; Arthur Caplan & Alison Bateman-House, “The FDA is an Integral Part of Compassionate Use,” *Forbes* (6 July 2017), online: <www.forbes.com/sites/arthurcaplan/2017/07/06/the-fda-is-the-most-important-part-of-compassionate-use/amp/> (noting that even well-meaning health professionals attempting to access an experimental drug without the FDA “may not know to look out for certain side effects—because the only people who know about them are employees at a rival company that’s testing a similar product and the FDA staffer to whom they had to report them. And in the worst-case scenarios, the doctor may not be brilliant or well-meaning but rather looking to sell to a patient an investigational medicine in which he has a financial stake or even that he outright knows is a piece of junk.”)

79. Ed Silverman, “Lawmaker Plans a Bill to Force Pharma to Disclose Compassionate Use Info,” *Wall Street Journal: Pharamlot* (blog) (31 October 2014), online: <blogs.wsj.com/pharamlot/2014/10/31/lawmaker-plans-a-bill-to-force-pharma-to-disclose-compassionate-use-info/>.

that finding such policies were difficult if not impossible to discern,⁸⁰ Congress included a provision in the *21st Century Cures Act* to make drug makers' policies more transparent and accessible.⁸¹ Unlike the Goldwater model legislation that is aimed at removing the FDA from requests for experimental drugs, the *Cures* mandate requires drugmakers to make their policies on compassionate use of experimental drugs public available through such means as posting the policy on the company website.⁸²

Additionally, ethicists and health professionals argue that right-to-try laws create false expectations for patients,⁸³ especially since patients may not realize even under right-to-try laws, "[d]rug companies don't have to give them the medicine, and insurance companies don't have to pay for it."⁸⁴ Patients seeking aid through the right to try are in a very different situation than those in clinical trials, which may provide statutory protections and contractual guarantees. The *Affordable Care Act (ACA)*⁸⁵ and most states⁸⁶ require insurers to cover routine costs such as physician and hospital visits for patients in clinical trials. Other costs—such as procedures, tests, and

80. Silverman, *supra* note 31. In a survey by the consulting firm Avalere Health, only 19 of 100 drug makers had publicly available policies about how to request access to experimental medicines. Brenda Huneycutt, Nina Mermelstein & Gillian Woollett, "Current State of Transparency of Manufacturer's Compassionate Use Policies" (October 2016) at 2, online: <<http://go.avalere.com/acton/attachment/t/12909/f-0354/1/-/-/-/20161010/%20Transparency%20of%20Compassionate%20Use%20Policies.pdf>>.

81. *21st Century Cures Act*, Pub L No 114-255 §3032, 130 stat 1033 at 1100 (2016); see *supra* notes 2-3.

82. *Ibid.* The policy posting must include contact information for compassionate-use requests; instructions on making such requests; information on how such requests are evaluated; and links to clinical trial information. But posting the drug maker's policy does "not serve as a guarantee of access to any specific investigational drug by any individual patient," nor does it preclude the drug maker from changing its policy.

83. See notes 76-87.

84. Carrie Feibel, "Patients Demand The 'Right To Try' Experimental Drugs, But Costs Can Be Steep," *NPR Shots* (3 March 2017), online: <www.npr.org/sections/health-shots/2017/03/03/517796956/patients-demand-the-right-to-try-experimental-drugs-but-costs-can-be-steep>; NYU Langone Health Working Group, *supra* note 56. ("Because drug makers aren't required to grant access to their investigational products, the laws create the false hope in desperately ill people that they can obtain something they may, in fact, not be able to get. And, some state right to try laws strip patients who use right to try of important benefits, such as health insurance or access to home healthcare.") *Supra* note 67, S 204 §2(a) references FDA regulations, 21 CFR §312(d)(1), that allow a drug maker to recover "direct costs" for supplying an experimental drug. See the text preceding footnote 71 above.

85. 42 USC § 300gg-8; National Cancer Institute, "Insurance Coverage and Clinical Trials," (22 June 2016), online: <www.cancer.gov/about-cancer/treatment/clinical-trials/paying/insurance>. However, some providers have argued insurers are not following this mandate. Christine Mackay et al, "Insurance denials for cancer clinical trial participation after the Affordable Care Act mandate" (2017) 123:15 *Cancer* 2893.

86. Kelly Johnson, "Payers Still Denying Coverage Despite Clinical Trial Mandate," *OncLive* (29 March 2016), online: <www.onclive.com/publications/oncology-business-news/2016/april-2016/payers-still-denying-coverage-despite-clinical-trial-mandate?p=2>.

therapies specifically related to the clinical trial—generally are covered by the drugmaker or the sponsor of the clinical trial.⁸⁷

II. *The right to die and related issues*

In contrast to the right to try, recognition of a “right to die” has been much less successful politically, and the debate has been handled very differently in the states than at the federal level. At one end, a handful of states have allowed patients to seek medical assistance to end their own life when they are afflicted with a terminal, debilitating illness. But even efforts to ensure that individuals understand their options at the end of life and plan for such situations have led to angry, misleading rhetoric.

1. *Federal law and policy*

While the policy-making arms of the federal government have been swayed by changes in the political environment, federal law and policy consistently have attempted to encourage individuals to think through their wishes for the end of their lives but stopped well short of medical-aid-in-dying. The following section explores the key policies and decisions framing—and limiting—an individual’s right to die from a federal perspective.

a. *Federal jurisprudence: no recognition of a constitutional right*

In terms of judicial decisions, the courts have recognized that individuals have a general right to refuse medical treatment.⁸⁸ In the seminal *Quinlan* decision, the New Jersey Supreme Court grounded that right to refuse in its finding of the right to privacy within the U.S. Constitution.⁸⁹ But more commonly, “most courts have based a right to refuse treatment either solely on the common-law right to informed consent or on both the common-law right and a constitutional privacy right.”⁹⁰ In other words, if an individual had a right to refuse to be touched, as the touch would constitute common-law battery, then a physician who performed an operation on an unwilling patient without consent similarly committed a battery.⁹¹

The Supreme Court furthered this analysis in *Cruzan* when the parents of Nancy Cruzan, a woman in a vegetative state, sued the state of Missouri in order to halt her life-sustaining treatment.⁹² While the Court assumed for purposes of the case that a *competent* person could permissibly refuse life-sustaining treatment under the Constitution, Cruzan here was not

87. *Ibid.*

88. *Cruzan v Missouri Dept of Health*, 497 US 261 at 270 (1990).

89. *In re Quinlan*, 355 A(2d) 647 (NJ 1976).

90. *Cruzan*, *supra* note 88 at 271.

91. *Ibid* at 269.

92. *Ibid* at 266-268.

competent to make such a decision and thus Missouri could seek to ensure a decision to remove life-sustaining medical assistance was being made in accordance with her wishes.⁹³ The Court found that a surrogate could make that decision for her but Missouri could require that the surrogate must demonstrate they were acting in accordance with what her wishes would have been had she been competent.⁹⁴

Although the Supreme Court has recognized that individuals can refuse medical treatment, including life-sustaining care, the Court has rejected claims that a right to die can be found in our federal Constitution in a pair of 1997 cases, finding that neither the Equal Protection Clause⁹⁵ nor the Due Process Clause⁹⁶ in the Fourteenth Amendment provided a basis for such a right. The Court noted that there was no history, tradition, or practice in support of medical aid in dying; rather, even though states were moving away from punishing suicide, they had “engaged in serious, thoughtful examinations of physician-assisted suicide and other similar issues” and had decided not to revise prohibitions on such assistance.⁹⁷ While *Cruzan* acknowledged that a mentally-competent individual with a terminal illness could reject life-sustaining treatment, such a request was not rooted in “personal autonomy” at the end of life but “the long legal tradition protecting the decision to refuse unwanted medical treatment”—in other words, an individual has the ability to reject any medical treatment, and that ability is not contingent on whether he is dying.⁹⁸

Relatedly, the Court rejected the theory that a patient who rejects life-sustaining treatment should be treated the same as a patient who seeks medical aid in dying, and therefore criminalizing assisted suicide was a violation of the Equal Protection Clause: “when a patient refuses life-sustaining medical treatment, he dies from an underlying fatal disease or pathology; but if a patient ingests lethal medication prescribed by a physician, he is killed by that medication.”⁹⁹ Further, a person may reject medical treatment for very different reasons than why another person might seek medical aid in dying.¹⁰⁰

93. *Ibid* at 279-281.

94. *Ibid* at 281-87.

95. *Vacco v Quill*, 521 US 793 (1997).

96. *Washington v Glucksberg*, 521 US 702 (1997).

97. *Ibid* at 716-719; Tom Beauchamp, “The Right to Die as the Triumph of Autonomy” (2006) 31:6 *J Medicine & Philosophy* 643 at 648.

98. *Glucksberg*, *supra* note 96 at 725.

99. *Vacco*, *supra* note 95 at 801.

100. *Ibid* at 802.

b. *Federal policies around end-of-life options*

Several federal policies on end-of-life decisions were made in reaction to these judicial decisions. For example, following *Cruzan*, Congress passed the *Patient Self-Determination Act (PDSA)*,¹⁰¹ which required certain providers to inform patients about advance directives and to ensure a patient's advance directive, if one existed, was included as part of the patient's records.¹⁰² Second, Congress subsequently moved to restrict medical aid in dying by passing the *Federal Assisted Suicide Funding Restriction Act*¹⁰³ just months prior to the Court's *Glucksberg* and *Vacco* decisions.¹⁰⁴ The Act prohibits the use of federal health funding "to cause (or assist in causing) the suicide, euthanasia, or mercy killing of any individual" except in cases where the individual sought to withdraw medical treatment.¹⁰⁵ Additionally, this law amended the *PDSA* to prohibit providers from notifying individuals about any state policies on physician-aid-in-dying.¹⁰⁶

Other federal policy considerations of end-of-life issues have focused more on the provision of care such as hospice or on issues similar to the *PDSA* such as advance care planning and counseling.¹⁰⁷ Proponents note that pursuing such policies would enable patients to receive the care they want at the end of life.¹⁰⁸ However, even these policy proposals sometimes lead to political uproars, which consequently causes a political retreat from pursuing such policies.¹⁰⁹ Following federal intervention into a dispute between the parents and the husband of a woman in a vegetative state over whether to withdraw her treatment,¹¹⁰ Congress passed legislation including advance care planning as part of an initial "Welcome to Medicare"

101. *Omnibus Budget Reconciliation Act of 1990*, Pub L No 101-508 § 4206, 104 Stat 1388 at 115-117.

102. US, Government Accounting Office, *Patient Self-Determination Act: Providers Offer Information on Advance Directives but Effectiveness Uncertain*, (GAO/HEHS-95-135) (1995).

103. Pub L No 105-12, 111 Stat 23 (codified at 42 U.S.C. § 14401 et seq).

104. National Center for Public Policy Research, "The Assisted Suicide Funding Restriction Act of 1997," online: <web.archive.org/web/20171009162621/http://nationalcenter.org/AssistedSuicide397.html> (noting that the law was passed in response to "federal courts of appeal [having] declared a constitutional right to assisted suicide" prior to the Supreme Court's reversals).

105. *Supra* note 103 at § 2(b).

106. *Ibid.*

107. US, Institute of Medicine, *Dying in America: Improving Quality and Honouring Individual Preferences Near the End of Life* (Washington DC: The National Academies Press, 2015) at 1-3.

108. Vyjeyanthi Periyakoil et al, "Do Unto Others: Doctors' Personal End-of-Life Resuscitation Preferences and Their Attitudes toward Advance Directives" (2014) 9:5 *PLOS One* e98246 at 1-2.

109. Peter Ubel, "Why It Is So Difficult to Kill the Death Panel Myth," *Forbes* (9 January 2013), online: <www.forbes.com/sites/peterubel/2013/01/09/why-it-is-so-difficult-to-kill-the-death-panel-myth>.

110. Josh Sanborn, "How Terri Schiavo Shaped the Right-to-Die Movement," *Time* (31 March 2015), online: <www.time.com/3763521/terri-schiavo-right-to-die-brittany-maynard/>.

benefit for new Medicare beneficiaries.¹¹¹ Just two years later, a political firestorm erupted when conservative activists mischaracterized attempts to allow Medicare to pay for advance care planning in an early version of the *Affordable Care Act (ACA)*.¹¹² *ACA* opponents argued that providing end-of-life counseling would incentivize physicians to push vulnerable patients to opt for less care.¹¹³ Other opponents tapped into a general fear of a “government takeover” of healthcare to argue that the *ACA* would lead to a government-run system, and the counseling provision would lead to “death panels” where government bureaucrats would ration care for older, sicker patients against their will.¹¹⁴ Ultimately, the federal government did authorize reimbursement for physicians to counsel Medicare beneficiaries about advance care planning as part of a larger payment regulation without much controversy.¹¹⁵

2. *State law and policy*

Proponents also have pursued policies at the state level to assist terminally ill patients. One reason that the debates have occurred at the state level may be due to our federalist system and the balance of powers between states and the federal government: states traditionally regulate the scope of medical services and liability issues, and medical assistance in dying would fall squarely in this area.¹¹⁶ But another reason that some of these efforts have been successful is because of the environments in different states; generally, proponents have been only been successful in states that could be described either as more politically and culturally liberal than the country as a whole or as having more of a libertarian bent.¹¹⁷ But even other “liberal” states such as Massachusetts and Maryland have failed to pass aid-in-dying proposals.¹¹⁸ Only a handful of jurisdictions have

111. Kaiser Family Foundation, “Medicare’s Role in End-of-Life Care,” (26 September 2016), online: <kff.org/medicare/fact-sheet/10-faqs-medicare-role-in-end-of-life-care/>.

112. US, Bill HR 3962, *Affordable Health Care for America Act*, 11th Cong, 2009.

113. Regina Lawrence & Matthew Schafer, “Debunking Sarah Palin: Mainstream news coverage of ‘death panels’” (2011) 13:6 Journalism 766.

114. *Ibid*; Sherrie Dulworth, “From Schiavo to Death Panels: How Media Coverage of End-of-Life Issues Affects Public Opinion” (2014) 58:2 NYL Sch L Rev 391.

115. Kaiser Family Foundation, *supra* note 111; Paula Span, “A Quiet End to the ‘Death Panels’ Debate,” *New York Times* (20 November 2015), online: <www.nytimes.com/2015/11/24/health/end-of-death-panels-myth-brings-new-end-of-life-challenges.html>.

116. George Annas, “Congress, Controlled Substances, and Physician-Assisted Suicide—Elephants in Mouseholes” (2006) 354:10 New Eng J Med 1079 at 1082-1084; Beauchamp, *supra* note 97 at 647.

117. While some of the states that have adopted a right to die by statute or ballot initiative may be considered politically liberal, some of the states—Colorado and Montana—might be better characterized as libertarian.

118. Dulworth, *supra* note 114; Anna Hiatt, “It’s Not That I Want to Die. It’s That I Want to Control My Own Suffering,” *Washington City Paper* (24 July 2015), online: <www.washingtoncitypaper.com/news/article/13047034/death-with-dignity-in-maryland>.

legislated or passed via popular referendum a right to allow terminally-ill individuals the ability to seek medical assistance in dying: California,¹¹⁹ Colorado,¹²⁰ Hawaii,¹²¹ Oregon,¹²² Vermont,¹²³ Washington,¹²⁴ and the District of Columbia.¹²⁵ Generally following the statutory framework adopted by Oregon, the first state to pass such a law, these state aid-in-dying laws contain similar safeguards and eligibility requirements to ward off abuse and coercion.¹²⁶ Under the Oregon model, eligible patients must be a competent adult with a terminal illness, or a prognosis of six month or less of life as confirmed by two physicians.¹²⁷ The patient must follow a specific process to request the medication but can rescind the request at any time.¹²⁸ Eligible patients cited the loss of autonomy due to the illness as the most common reason that they requested medical assistance.¹²⁹ Some patients who go through the entire process never take the medication at all, suggesting that having the medication and thus the choice to utilize it brings a sense of autonomy to the patient.¹³⁰

Finally, Montana is currently the only state to have recognized a similar right through litigation after the state supreme court held that physicians do not violate state law if they assist patients in dying.¹³¹ In analyzing the

119. US, AB 15, *End of Life Option Act*, 2015-2016, 2d Extra Sess, Cal. A state court struck down the law due to a violation of the legislative process, and the case is currently on appeal. Scott Neuman, "Court Upholds Ruling Against California's Assisted Suicide Law," NPR: *The Two-Way* (24 May 2018), online: <www.npr.org/sections/thetwo-way/2018/05/24/613940700/court-upholds-ruling-against-californias-assisted-suicide-law>.

120. US, Prop 106, *End of Life Options Act*, 2016, Colo (passing by voter referendum).

121. US, SB 1129, *Medical Aid in Dying Act*, 29th Legis, 2017, Hawaii.

122. 3 ORS § 127.800 (2017).

123. 18 VSA § 113.5281 as amended by S 108, *Act. 27*, 2015-2016, Reg Sess, Vt (removing sunset date of 2015 in originally legislation).

124. 70 Wash Rev. Code § 245 (2017) (2008) (passing by voter referendum in November 2008).

125. 7 DC Code § 661.01 (2017).

126. Death with Dignity National Center, "How do Aid-In-Dying Laws Protect Patients?," online: <www.deathwithdignity.org/faqs/#safeguards>.

127. *Ibid.*

128. *Ibid.*

129. Charles Blanke et al, "Characterizing 18 Years of the Death With Dignity Act in Oregon" (April 2017) *JAMA Oncology* 1403 (finding that 92% of patients cited loss of autonomy, nearly 90% cited the inability to "participate in enjoyable activities," and nearly 79% cited loss of dignity as reasons for requesting aid in dying).

130. Chuck Gormley, "Physician-aided deaths continue to rise in Oregon," *HEM/ONC Today* (6 April 2017), online: <www.healio.com> (noting that some "patients do not take the medication prescribed. Nonetheless, having the prescription still benefits the patient in terms of having control over his or her life or death.")

131. *Baxter v State*, 224 P(3d) 1211 (Mont 2009). Although a New Mexico state court ruled that a law prohibiting medical aid in dying was unconstitutional, the state supreme court reversed, declining to find a "constitutional right to a physician's aid in dying." *Morris v Brandenburg*, 376 P(3d) 836 at 839 (N Mex 2016); Scott Sandlin, "New Mexico Assisted Suicide Law Affirmed," *Albuquerque Journal* (30 June 2016), online: <www.abqjournal.com/801082/nm-supreme-court-rules-on-aid-in-dying-workers-comp.html>.

state statute on “deliberate homicide,” the Montana Supreme Court noted the statute recognizes the consent of the victim as a potential defense if, among other elements, such a consent is not “against public policy.”¹³² The Court noted Montana had passed the *Montana Rights of the Terminally Ill Act*,¹³³ which did not include physician-aid-in-dying¹³⁴ but did “very clearly provide[] that terminally ill patients are entitled to autonomous, end-of-life decisions, even if enforcement of those decisions involves direct acts by a physician” such as removing life-sustaining treatment.¹³⁵ Thus, the Court found the *Terminally Ill Act* did not contravene public policy and a physician would be able to claim a consent defense against a homicide charge.¹³⁶ However, since the *Baxter* decision, Montana has not established a regulatory scheme to regulate medical aid-in-dying nor has it amended state law to overturn *Baxter* legislatively.¹³⁷

Paralleling the question of whether federal law could preempt state right-to-try laws, there is an open question whether the federal government could intervene in state medical-aid-in-dying programs.¹³⁸ Noting *Glucksberg*’s praise in favor of states debating medical aid in dying,¹³⁹ the Supreme Court’s review of a Justice Department regulation, which would have criminalized Oregon’s aid-in-dying program, turned narrowly on its interpretation of the federal *Controlled Substances Act*.¹⁴⁰ Although the Court noted that states traditionally regulated what was a “legitimate medical purpose,” its decision turned on “the statute’s text and design.”¹⁴¹ Thus, Congress could modify the statute in an attempt to overturn the Court’s decision.¹⁴² Additionally, because of Congress’s authority over the

132. *Baxter*, *ibid* at 1215.

133. 50 Mont ch 9 § 204 et seq.

134. For a discussion of the Montana law, see “Montana Euthanasia Laws,” *Findlaw*, online: <statelaws.findlaw.com/montana-law/montana-euthanasia-laws.html>.

135. *Baxter*, *supra* note 131 at 1217.

136. *Ibid* at 1220.

137. “Montana,” Death with Dignity National Center, online: <www.deathwithdignity.org/states/montana/>.

138. Annas, *supra* note 116 at 1083 (noting “there is no longer any serious question that Congress has the authority under the Commerce Clause to regulate the practice of medicine”).

139. *Gonzales v Oregon* 546 US 243 at 253-254 (2006) (referring to *Glucksberg*, *supra* note 97 at 735. (“Throughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue, as it should in a democratic society.”))

140. *Gonzales*, *ibid* at 253-254.

141. *Ibid* at 269-270.

142. Annas, *supra* note 116 at 1083-1084.

District of Columbia's budget,¹⁴³ some representatives have attempted to override its aid-in-dying law.¹⁴⁴

III. *Comparing and contrasting the right to try with the right to die and related policies*

Given both "rights" present different choices for those at the end of life, there are questions about whether both choices should be given some level of equivalency or whether it is fair to give one more weight than the other. Are they not both attempting to give someone at the end of life a range of options? While the right to try has its flaws,¹⁴⁵ its successes should be studied to understand whether there are political, ethical, or legal arguments that proponents of right-to-die proposals can adopt to advance their ideas.

1. *Policy and ethical considerations*

On one hand, several similarities are readily evident between the right to try and the right to die. First, as a process matter, both involve an affirmative request for a drug that is outside its either known or intended use. Our general public health interest is for drugs to cure, not to harm.¹⁴⁶ The FDA's role in the drug approval process is built on this interest. But in medical-aid-in-dying programs, the drug is used to end a life. In instances of a right to try, the patient's hope is that an experimental drug will be curative, but given the experimental nature, we cannot be sure the drug will achieve this hoped-for purpose because it has not been proven safe and effective.¹⁴⁷ Indeed, an experimental drug could be harmful and worsen a terminally-ill patient's condition.¹⁴⁸

Second, supporters of either right often ground their arguments in the concepts of self-determination and personal autonomy: if an individual is dying, then they should be able to take their final steps on their own

143. Mark Richards, "A Citizen's Guide to the Congressional Appropriations Process for the District of Columbia," DC Vote (February 2002), online: <www.dcvote.org/public-opinion/citizens%E2%80%99-guide-congressional-appropriations-process-district-columbia>. This power distinguishes congressional authority over the District in contrast to the debate in *Gonzales v. Oregon*, 546 US 243 (2006).

144. Death with Dignity National Center, "District of Columbia," online: <www.deathwithdignity.org/states/district-of-columbia/>; Jenna Portnoy & Peter Jamison, "House Committee Advances Measure to Block Assisted Suicide in D.C.," *Washington Post* (14 July 2017), online: <www.washingtonpost.com/local/dc-politics/house-committee-advances-measure-to-block-assisted-suicide-in-dc/2017/07/14/72166bde-67f5-11e7-a1d7-9a32c91c6f40_story.html?utm_term=.C5e71672C252>.

145. *Supra* notes 76-87; Kaplan, *supra* note 78; David Farber et al, "How State Right-To-Try Laws Create False Expectations" (22 May 2017) *Health Affairs* (blog), online: <healthaffairs.org/blog/2015/05/22/how-state-right-to-try-laws-create-false-expectations/>.

146. See *supra* notes 10-16.

147. See *supra* notes 16-18.

148. See *supra* notes 76-78.

terms.¹⁴⁹ Of course, this rationale glosses over the fact that the individual cannot accomplish his goal on his own—he needs the assistance of a health professional and of medication to effectuate his goal.¹⁵⁰ Indeed, the Court noted this affirmative need as a basis for differentiating between medical aid in dying and withdrawing life-sustaining treatment.¹⁵¹ The reliance on the actions of a health professional of course raise additional issues such as the professional's concerns about liability and professional responsibilities as well as ethical views on administering a lethal or an experimental drug to a patient.¹⁵² In the right-to-try context, a patient successfully exercising such a right also may impinge on the success of a clinical trial and the welfare of the trial's participants—and future patients—if there are limited quantities of the experimental drug.¹⁵³

Third, both rights fulfill a need for closure. On one hand, if the individual is allowed access to an experimental drug, at least he will know whether that drug would have made any difference.¹⁵⁴ Many advocates for a right to try noted that their advocacy was driven by not knowing the answer to that question.¹⁵⁵ On the other hand, if an individual is seeking medical aid in dying, she will achieve closure in ending a struggle with a terminal illness or condition on her own terms, rather than on the disease or condition's progression.¹⁵⁶ Similarly, both rights may be seen as achieving the ethical notion of mercy as in both situations, society is attempting to find

149. Compare Blanke, *supra* note 129 (noting autonomy as the most cited reason for patients to seek state program for medical aid in dying) with Corieri, *supra* note 32 at 1. ("Patients should be free to exercise a basic freedom—attempting to preserve one's own life.") There also are other areas where states allow a competent individual to elect state aid in ending his life. Melanie Walthour, "Competently, Knowingly, and Voluntarily Dying with Dignity: Why States that Allow Defendants to Volunteer for Execution Should Allow Terminally Ill Patients to Die in a Dignified and Humane Manner" (2016) 9:2 *Ariz Summit L Rev* 437 at 439 (comparing medical aid in dying to states allowing defendants sentenced to execution to waive their appeals).

150. Beauchamp, *supra* note 97 at 648.

151. Glucksberg, *supra* note 96 at 725-726. ("Pointing to Casey and Cruzan, respondents read our jurisprudence in this area as reflecting a general tradition of 'self-sovereignty,' and as teaching that the 'liberty' protected by the Due Process Clause includes 'basic and intimate exercises of personal autonomy.' The right assumed in Cruzan, however, was not simply deduced from abstract concepts of personal autonomy."); Beauchamp, *supra* note 97 at 648 (noting the right to die "shifted... from *refusals* of medical technologies to *requests* for aid in hastening death"). Compare this result though with Baxter, which is the only case to affirm medical-aid-in-dying through a statutory, not constitutional, interpretation. *Baxter*, 224 P(3d) at 1211 (finding "an apt statutory starting point for understanding the legislature's intent to give terminally ill patients...end-of-life autonomy, respect and assurance that their life-ending wishes will be followed").

152. Meyerson, *supra* note 8 at 395, 398.

153. Caplan, *supra* note 78.

154. Corieri, *supra* note 32 at 1; Tedeschi, *supra* note 77.

155. *Ibid.*

156. *Supra* notes 118-130.

a way to end—or potentially end— suffering.¹⁵⁷ Even if an experimental drug does not work, the argument is that at least an individual may feel both closure and mercy by knowing a dying wish was fulfilled.¹⁵⁸

Other end-of-life policies such as advance care planning can also provide a sense of closure as counseling and planning can help us understand and work through the consequences of our choices about the end of life. Simply going through advance care planning does not necessarily mean that an individual will choose a “do not resuscitate” or similar option,¹⁵⁹ but it does make one realize that choosing a path that extends life might not extend it in a way that we all may be comfortable with.¹⁶⁰ Through such counseling, individuals may have a better understanding of the risks and success rates of different medical inventions and having this knowledge will give them a say in how they want to receive care at the end of their life and what they feel makes a life worth living.¹⁶¹ It may also give them peace of mind by relieving loved ones of having to make these difficult decisions for them.¹⁶²

On the other hand, the ultimate difference between the two rights is finality.¹⁶³ With the right to try, if I am terminally ill but do not successfully respond to an experimental drug, I will succumb to my illness.¹⁶⁴ With the

157. Compare Corieri, *supra* note 32 at 1 (quoting a parent who did not receive compassionate-use approval before his daughter died, “I don’t know that either of these drugs would have saved [her] life, but wouldn’t it be nice to give her a chance?”) with Hiatt, *supra* note 118 (quoting testimony from a supporter of a Maryland bill to allow medical aid in dying, “We are dying in pain, and we want control over our end.”)

158. See the text accompanying note 154 above.

159. Institute of Medicine, *supra* note 107 at 12. (“People who capture their care preferences in discussion or writing most commonly choose care that focuses on improving quality of life.”)

160. *Ibid.* (“In the absence of adequate documented advance care planning, the default decision is to treat a disease or condition, no matter how hopeless or painful. A result of inadequate advance care planning, therefore, can be more intensive treatment, as well as more negative impacts on family members.”); Periyakoil, *supra* note 108 at 7-8.

161. Institute of Medicine, *supra* note 107 at 12.

162. *Ibid.*; Periyakoil, *supra* note 108 at 1-2.

163. Note that the Johnson bill is different from most right-to-try laws and the competing House proposal because it uses the term “life threatening” rather than terminal. See the text accompanying note 69 above. Given that this term could apply to “diseases that are life-threatening, but not immediately life-threatening,” it is unclear how this language will apply in practice even though it did not seem to undermine the political messaging of the bill being a means for ending only the terminally ill. Firth, *supra* note 77 (quoting FDA Commissioner Gottlieb).

164. However, it may not be possible to know what the health consequences of taking an experimental drug will be, particularly to a body that is succumbing to a fatal disease or condition. An individual could experience great harm or even death from taking an experimental drug.

right to die, the consequences are more obvious and final.¹⁶⁵ Even in cases where a patient obtains medication to end his life but does not utilize it, that individual still is making a final decision through having the drug accessible and at the ready.¹⁶⁶

Moreover, the right to try may not provide finality since it does not create enforceable rights: the drugmaker and the insurer do not have any obligation under any right-to-try legislation to provide access to the drug or pay for the services that may be necessary to administer it.¹⁶⁷ Because there are no such requirements, ethicists have noted that right-to-try laws not only give patients the false hope that they might be cured of their illness but also that they will receive experimental drugs in the first place.¹⁶⁸ What then is the next step for a terminally ill patient if a drugmaker denies a request for access to an experimental drug? If it is meaningless to create a hollow right that has no means of enforcement, would not the next logical step be to require pharmaceutical companies to allow all terminally ill patients access to experimental drugs?¹⁶⁹ Such a proposal would have to address issues around cost (who will pay for the experimental drug? who will pay to administer it?), liability (does the patient and his family have no legal recourse if the health professional fails to administer the dose correctly?), and process (how does such use figure into a clinical trial? do poor results need to be included?). But the right to try does fit in with our notions of hope—whether false or not—and our society's tradition that medicine should be to heal. That explains in part why lawmakers are more ready to pass right-to-try laws, which create some sense of hope even if that hope is artificial.¹⁷⁰

2. *Legal questions arising from the political and ethical similarities*

Given that there are similarities that can be drawn from comparing these two statutory rights, proponents of a right to die should question whether the legislature can favour one set of wishes over another at the end of life. Initially, it would seem that there is no constitutional issue similar to *Vacco*

165. The Supreme Court suggested as much when it rejected finding a right to die within the Constitution and pointed to the legislature for guidance. *Supra* note 95-101. "Public concern and democratic action are therefore sharply focused on how best to protect dignity and independence at the end of life, with the result that there have been many significant changes in state laws and in the attitudes these laws reflect." Glucksberg, *supra* note 96 at 716.

166. *Supra* notes 129-130.

167. *Supra* notes 76-87.

168. Farber, *supra* note 145.

169. Okie, *supra* note 47 at 439 (discussing a prior effort to give terminally-ill patients a broader right of access to experimental drugs that had only gone through the first stage of clinical trials).

170. Tedeschi, *supra* note 77. ("It's hard to argue against when it's framed as the terminally ill having the right to save their lives.... How do you argue against that?")

v. Quill, where the Supreme Court found that there was no equal-protection violation when a state distinguished between terminally ill patients who refuse medical treatment with those that want medical aid in dying.¹⁷¹ The Court found these situations were different because “when a patient refuses life-sustaining medical treatment, he dies from an underlying fatal disease or pathology; but if a patient ingests lethal medication prescribed by a physician, he is killed by that medication.”¹⁷² The Court reasoned a patient’s rationale for rejecting treatment may be very different from someone seeking aid in dying and thus a state could ban such assistance without violating the Equal Protection Clause.¹⁷³

Yet the two classes discussed in *Vacco* are different from the two classes in that case. Here, a legislature is allowing someone to receive drugs (experimental and not FDA-approved) in hopes of a curative outcome but not receive drugs (being used outside its FDA-approved curative intent) for the purpose of dying. With the “right to try” measures, policymakers are arguably creating a division among the terminally ill as some can make a choice for assistance where others cannot.

Something feels “unequal” in allowing some terminally ill patients to choose one path but not the other. Are these not two similar classes of individuals, those at the end of life seeking drugs outside a federally-approved process? After all, as one California proponent of the right to try argued, if a state allowed the right to die, it should allow the right to try.¹⁷⁴ Wouldn’t the opposite be true as well? But where legislatures have passed a right to try, they have created a right only for certain patients only for one reason: to extend life potentially. That reason is a very powerful rationale for making the division of course and might be enough to survive a legal challenge.

Conclusion

The right to try and the right to die both stem from the same rationale: we should honour individuals’ wishes at the end of their life, and society ought to show mercy to those who are dying. Yet even though these two proposals may share similar rationales, they have been viewed quite differently in the policy and legislative arena.

171. *Vacco v Quill*, *supra* note 95 at 802-803.

172. *Ibid* at 801.

173. *Ibid*.

174. Feibel, *supra* note 84 (quoting the bill sponsor, Assemblyman Ian Calderon, that “[i]t’s inhumane to have a law on the books that allows you to end your own life, but no law on the books that allows you to fight to extend it”).

The success of the right to try suggests that proponents of other end-of-life policies—whether from the right to die to or even just seeking to ensure that individuals have greater access to end-of-life counseling—ought to see whether they can make their arguments in the political and legal arenas by grounding them in these shared rationales. After all, people who can access all the information about end-of-life planning might still, in the end, choose to receive the full extent of care possible to extend their lives. But only with the end-of-life information that advance care planning provides is the choice truly meaningful and respectful.

DALHOUSIE LAW JOURNAL

Volume 41

Number 1

Spring 2018

End-of-Life

Physicians' Attitudes, Concerns, and Procedural Understanding
of Medical Aid-in-Dying in Vermont

Teresa Ditommaso, Ari P. Kirshenbaum and Brendan Parent

Foreseeably Unclear: The Meaning of the "Reasonably
Foreseeable" Criterion for Access to Medical Assistance
in Dying in Canada

Jocelyn Downie and Kate Scallion

Legalizing Assisted Dying: Cross Purposes and Unintended
Consequences

Emily Jackson

Trying and Dying: Are Some Wishes at the End of Life
Better Than Others?

Oliver J. Kim

A Comparative Analysis of Voluntariness Safeguards and
Review Procedure under Oregon and the Netherlands'
Physician Assisted Dying Laws

Michaela Estelle Okninski

Euthanasia by Organ Donation

Michael Shapiro

Questioning POLST: Practical and Religious Issues

Lloyd Steffen

Legal History and Rights for Nonhuman Animals:
An Interview with Steven M. Wise

Angela Fernandez

The Stakes in Steak: Examining Barriers to and Opportunities
for Alternatives to Animal Products in Canada

Angela Lee

The Animal Protection Commission: Advancing Social Membership
for Animals through a Novel Administrative Agency

John MacCormick

